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10/544,088	01/10/2006	Jianming Chen	133697-0002	8599

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
12/01/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/544,088	CHEN ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1-10-06; 7-29-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response to the election requirement dated 10-19-09 is acknowledged.

Upon consideration, the restriction requirement is withdrawn.

Claims included in the prosecution are 1-20.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to what applicant intends to convey by 'asiaticoside that is enwrapped in the middle of liposomal bilayer to form a hydrophilic opalescent suspension' as recited in claim 1. First of all, liposomes are made of lipids such as phospholipids and therefore, they are not hydrophilic. Liposomes are generally suspended in the hydrating medium which is hydrophilic. Furthermore, if the active agent which is encapsulated is lipophilic, then it would be in the bilayer, that is between the phospholipid molecules and not in the middle of the bilayer. Furthermore, it is unclear as to what the liposomes are made of as recited in claim 1. Reciting these components is essential since the dependent claim recites phospholipids such as lecithin, DSPC and DPPC as further comprising.

Step a) in claim 2 recites 'providing asiaticoside and a liposome'. It is unclear as to what applicant intends to convey by this expression. A careful review of the

specification indicates that the lipids and asiaticoside are dissolved in an organic solvent and then hydrated to produce liposomes and not by the way as recited in step a). Similar is the case with claim 10.

Claim 4 is confusing since it recites two ratios for asiaticoside and lipid components. Which is the limitation in the claim? Similar is the case with claims 11 and 12.

What is the distinction between distilled water or deionized water and purified water as recited in claims 6 and 14?

The last line in claim 10 recites "to produce an asiaticoside'. This is incorrect since what is produced is a liposome containing asiaticoside. What is meant by 'subjecting to microjet'?

What is conveyed by 'wherein asiaticoside-liposome comprises a cosmetic' in claims 9 and 20? The expression can be interpreted in two ways. 1) The composition is a cosmetic composition; 2) the liposomes further comprise a cosmetic encapsulated within.

Claims 2 and 10 are method claims and not product claims. If applicant's intent is to claim the product produced by the process is for pharmaceutical or cosmetic purposes, then claims 15-20 should be amended to recite such limitation.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 4, 9 and 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ji (Derwent 2002/233892).

Ji discloses niosomes containing both asiaticoside (40 %) and ceramide (abstract). Niosomes are non-ionic surfactant liposomes. Behan (5,156,766) is cited of interest in this context (see col. 1, lines 45-46).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denis (5,286,629) of record or Ravaux (6,416,768) in combination with Zysman (5,773,611), Park (6,372,236), Kitson (6,824,785) individually or in combination.

Denis discloses liposomal formulations for regeneration of epidermis and a method of preparation of liposomes. The liposomes contain asiaticoside, dipalmitoylphosphatidylcholine. The method of preparation involves dissolving the lipid and asiaticoside in an organic solvent, atomizing at about 60 degrees to give a powder and hydrating the powder with an aqueous medium to produce liposomes (Abstract, col. 2, lines 57-63, col. 6, lines 29-56, example 3).

Ravaux teaches vesicular compositions containing phospholipids and asiaticoside (abstract, col. 4, lines 21-22, col. 5, line 25).

What is lacking in Denis or Ravaux is ceramide in the liposomal compositions.

Zysman discloses the importance of skin ceramides and teaches the use of ceramides in liposomal formulations for the treatment of skin. The method of preparation involves combining the ceramide with other lipids, evaporating the solvent at 40 degrees and hydrating the lipid film with an aqueous medium (abstract, col. 1, line 11 through col. 3, line 47, col. 5, lines 7-53, Examples 1 & 2, and claims)

Park discloses the importance of ceramides and teaches and liposomal compositions containing ceramides. The method of preparation involves heating the lipid mixture and adding the aqueous medium (col. 1, line 10 through col. 2, lines 57, col. 3, line 1 through col. 4, line 63, Preparation example II on col. 5, Text examples on columns 6 and 7 and claims).

Kitson similarly teaches liposomes containing ceramides for skin barrier replacement (abstract, col. 1, line 7 through col. 6, line 37, Example 1 and example 4 and claims).

The inclusion of ceramides in the mixture of phospholipids and asiaticoside of Denis would have been obvious to one of ordinary skill in the art because of the importance of ceramide in topical formulations taught by Zysman, Park and Kitson

7. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bombardelli (5,166,139) of record in combination with Zysman (5,773,611), Park (6,372,236), Kitson (6,824,785) individually or in combination.

Bombardelli teaches pharmaceutical and cosmetic compositions containing phospholipids and asiaticoside for topical administration. The method of preparation involves mixing of asiaticoside and soy phosphatidylcholine or distearoylphosphatidylcholine in an organic solvent, heating the mixture and removing the organic solvent (abstract, columns 1-3, Tables 1 and 2 and claims).

Bombardelli does not however teach the hydration of the mixture of asiaticoside and phospholipids. Bombardelli also lacks the teaching of the inclusion of ceramide.

Zysman discloses the importance of skin ceramides and teaches the use of ceramides in liposomal formulations for the treatment of skin. The method of preparation involves combining the ceramide with other lipids, evaporating the solvent at 40 degrees and hydrating the lipid film with an aqueous medium (abstract, col. 1, line 11 through col. 3, line 47, col. 5, lines 7-53, Examples 1 & 2, and claims)

Park discloses the importance of ceramides and teaches and liposomal compositions containing ceramides. The method of preparation involves heating the lipid mixture and adding the aqueous medium (col. 1, line 10 through col. 2, lines 57, col. 3, line 1 through col. 4, line 63, Preparation example II on col. 5, Text examples on columns 6 and 7 and claims).

Kitson similarly teaches liposomes containing ceramides for skin barrier replacement (abstract, col. 1, line 7 through col. 6, line 37, Example 1 and example 4 and claims).

The inclusion of ceramides in the mixture of phospholipids and asiaticoside of Bombardelli would have been obvious to one of ordinary skill in the art because of the

importance of ceramide in topical formulations taught by Zysman, Park and Kitson. Hydration of the lipid mixture of Bombardelli would have been obvious to one of ordinary skill in the art since these references teach the formation of liposomes upon the addition of aqueous medium and since liposomes are art known sustained release vehicles.

8. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zysman (5,773,611) or Kitson (6,824,785) by themselves or in combination, in view of Shair (6,797,819).

Zysman discloses the importance of skin ceramides and teaches the use of ceramides in liposomal formulations for the treatment of skin. The method of preparation involves combining the ceramide with other lipids, evaporating the solvent at 40 degrees and hydrating the lipid film with an aqueous medium (abstract, col. 1, line 11 through col. 3, line 47, col. 5, lines 7-53, Examples 1 & 2, and claims). Zysman in addition teaches the inclusion of antioxidants as the active agents which include vitamin E (tocopherol) (col. 6, lines 53-59).

Kitson similarly teaches liposomes containing ceramides for skin barrier replacement (abstract, col. 1, line 7 through col. 6, line 37, Example 1 and example 4 and claims). Kitson in addition teaches the inclusion of antioxidants such as vitamin E (col. 5, lines 23-27).

Zysman and Kitson however, do not teach asiaticoside as the antioxidant.

Shair teaches that asiaticoside and vitamin E are antioxidants and they accelerate wound healing (col. 102, lines 64-67). Shair further teaches liposomes as carriers (col. 26, line 16).

It would have been obvious to one of ordinary skill in the art to use asiaticoside in the compositions of Zysman or Kitson with a reasonable expectation of success because of the equivalency between asiaticoside and vitamin E taught by Shair.

9. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denis (5,286,629) or Ravaux (6,416,768) in combination with Zysman (5,773,611), Park (6,372,236), Kitson (6,824,785) individually or in combination OR over Bombardelli (5,166,139) in combination with Zysman (5,773,611), Park (6,372,236), Kitson (6,824,785) individually or in combination both set forth above, further in view of Ji cited above.

The teachings of the primary references have been discussed above. One of ordinary skill in the art would be motivated further to encapsulate both asiaticoside and ceramide in the phospholipid liposomes with a reasonable expectation of success since the Ji teaches that both compounds could be encapsulated in niosomes (non-surfactant liposomes).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

GSK